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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,060	02/12/2002	David Mu	38002-0024	2406
26633	7590	11/15/2005	EXAMINER	
HELLER EHRMAN WHITE & MCAULIFFE LLP 1717 RHODE ISLAND AVE, NW WASHINGTON, DC 20036-3001			GIBBS, TERRA C	
			ART UNIT	PAPER NUMBER

1635

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/073,060	Applicant(s) MU ET AL.	
	Examiner Terra C. Gibbs	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,9-12,14,22-24,33-35 and 39-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,9,10,12,22,23,33,34 and 39-51 is/are allowed.
- 6) ☒ Claim(s) 3, 11, 14, 24, 35, and 52-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This Office Action is a response to Applicant's Amendment and Remarks filed September 1, 2005.

New claims 44-64 are acknowledged. Claims 2, 3, 10, 11, 12, 14, 22-24, 33-35, and 39-43 have been amended.

Claims 1-3, 9-12, 14, 22-24, 33-35, 39-43, and 44-64 are pending in the instant application.

Claims 1-3, 9-12, 14, 22-24, 33-35, 39-43, and 44-64 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

In the previous Office Action mailed December 8, 2004, claims 1-3, 9-12, 14, 22-24, and 33-35 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. **This rejection is withdrawn** in view of Applicant's arguments. Specifically, the Examiner is withdrawing this rejection in view of Applicant's arguments that.

Claim Rejections - 35 USC § 102

In the previous Office Action mailed December 8, 2004, claims 33-35 were rejected under 35 U.S.C. 102(b) as being anticipated by Zacharski et al. (Thromb Haemost, 1998 Vol. 79:876-877). **This rejection is withdrawn** in view of Applicant's amendment to the claims. Specifically, the Examiner is withdrawing this rejection in view of Applicants amendment to the claims to recite "a method for diagnosing a breast cancer". It is noted that Zacharski et al. disclose staining of normal tissue and tumor types, including ovarian cancer, adenocarcinoma, renal cancer, and squamous cell carcinoma of the lung.

In the previous Office Action mailed December 8, 2004, claims 1-3, and 39 were rejected under 35 U.S.C. 102(b) as being anticipated by Tanimoto et al. (Cancer Research, 1997 Vol. 57:2884-2887). **This rejection is withdrawn** in view of Applicant's arguments. Specifically, the Examiner is withdrawing this rejection in view of Applicant's arguments that Tanimoto et al. disclose the measurement of hepsin mRNA and not the measurement of hepsin gene copy number. The Examiner has also been persuaded by Applicant's arguments that hepsin mRNA does not necessarily correlate with hepsin gene copy number as evidenced by Table 2 in the instant specification.

Applicant's amendment necessitated the new ground(s) of rejection presented below:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 11, 14, 24, 35, and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 3, 11, 14, 24, 35, and 58 are drawn to a method for diagnosing a cancer in a mammal or a method for monitoring the efficacy of a therapeutic treatment regiment, comprising detecting and measuring hepsin gene copy number, hepsin mRNA, or hepsin protein and comparing data test gene copy number to control data gene copy number, wherein the data for the control gene copy number is in a data storage medium.

The term "data storage medium" does not appear to be recited anywhere in the instant specification. While Applicants have support for specific terms of electronic or paper format such as "paper", "electronic mail", "disk", "compact disk" (CD), "digital versatile disk" (DVD), "memory card", "memory chip", "tape", and "video", for example, Applicants do not have support for the term "data storage medium" because

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embodiments encompassing specific forms of electronic or paper format do not support the specific limitation "data storage medium". Furthermore, it is noted that in the response filed September 1, 2005, Applicants do not indicate where support can be found in the specification for the limitation "data storage medium".

Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP § 2163.06 which states, when filing an amendment, an applicant should show support in the original disclosure for new or amended claims (See MPEP § 714.02 and § 2163.06).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 52-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 52-58 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: How one would identify an amplification of the hepsin gene copy number where there is nothing to compare? It appears that the claims are missing a "control group" and a "test group", wherein the control is compared to the test, for example.

Claims 59-64 are drawn to a method for diagnosing a cancer in a mammal or a method of monitoring the efficacy of a therapeutic treatment regimen, comprising

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determining a first indirect measure of hepsin gene copy number that is suspected to be precancerous or cancerous and comparing the first indirect measure to a second indirect measure of a control gene copy number wherein a detectable change in the first indirect measure relative to the second indirect measure indicates the presence of a precancerous lesion or a cancer. The terms "a first indirect measure" and "a second indirect measure" are vague and indefinite because these terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention. Therefore, claim 59 and claims that depend therein are vague and indefinite.

Allowable Subject Matter

Claims 1, 2, 9, 10, 12, 22, 23, 33, 34, and 39-51 are allowable. Claims 1, 2, 9, 10, 12, 22, 23, 33, 34, and 39-51 are considered to be free of the prior art since the prior art does not teach or fairly suggest a method for diagnosing a specific cancer in a mammal or a method for monitoring the efficacy of a therapeutic treatment regimen, comprising detecting and measuring hepsin gene copy number, hepsin mRNA, or hepsin protein and comparing data test gene copy number to control data gene copy number, wherein an increase in the test, relative to the control, indicates the presence of a precancerous lesion or a cancer or wherein a decrease in the test, relative to the control, indicates the treatment regiment is effective.

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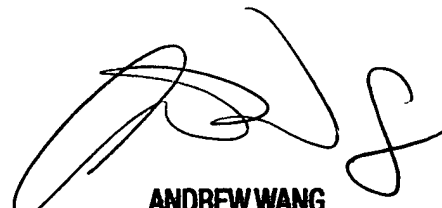
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tcg

November 8, 2005



ANDREW WANG
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